

A Study of Intrusion Characteristics of Low Viscosity Cement Simplex-P and Palacos Cements in a Bovine Cancellous Bone Model

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Aseptic loosening is the most common long-term complication of cemented total hip arthroplasties (THA). The functional longevity of these implants depends on the bone-cement interface. The influence of cement injection pressure, type of cement, ambient temperature, chilling of the monomer, and centrifugation of cement-on-cement intrusion depth was investigated in specimens of bovine cancellous bone. In order to validate the bovine model for comparative purposes relative to use in man, a linear relationship between human and bovine cancellous bone was first demonstrated for various porosities and cement intrusion depth. Three cements (Low Viscosity Cement [LVC], Simplex-P, and Palacos) were intruded at three different pressures (20, 40, and 60 PSI) at the same ambient temperature and relative humidity into commercially prepared plugs of bovine cancellous bone. Cement intrusion depth was proportional to injection pressure for all three cements, but was significantly different for each cement at a given pressure. At 20, 40, and 60 PSI, Palacos had a cement intrusion depth of 1.4, 2.4, and 2.8 mm respectively, while the figures for Simplex-P were 2.2, 4.2, and 5.0 mm, and for LVC were 8.0, 12.0, and 14.6 mm. Ambient temperature had an inverse relationship with cement intrusion

depth for all three cements given the same experimental conditions. Chilling the monomer increased the intrusion of Simplex-P to 5.8, 8.2, and 12.7 mm at 20, 40, and 60 PSI injection pressure respectively. Simplex-P intrusion depth was not modified by cement centrifugation at any of the three injection pressures tested. Cement intrusion depths obtained with three popular commercial cements were compared with respect to pressures, usually generated in the operating room, and prepared in various conditions in a bovine cancellous bone. In an experimental system, the cement intrusion depth obtained in conditions usually achieved in the operating room (60 PSI pressure, 22° ambient temperature, and 65% relative humidity) is greater than the remaining cancellous bone bed in the prepared human femoral canal. Cement centrifugation does not change cement intrusion depth. Notwithstanding the limitations of the experiment, the information seems clinically relevant.

Aseptic loosening is the most common long-term complication of total hip arthroplasty (THA). Femoral component loosening has been reported to be as high as 24% after five years and 30% after ten years using the traditional Charnley prosthesis.^{1,3-5,14,15} While factors other than those related to cement, such as overweight and over activity of the patient, varus position of the prosthesis, resorption of the calcar femorale, *etc.*, may contribute to loosening, suboptimal cement technique is a major cause of this complication.

Excessive micromotion at the cement-bone interface may lead to localized bone resorp-

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tion, cement microfracture, membrane formation, bone lysis, and ultimately aseptic loosening of the implant.⁹ The quality of this interface is dependent on the intrinsic qualities of the cement and on the characteristics of the cancellous bone bed (which are not under the control of the surgeon), and on the cement intrusion into that cancellous bone bed. According to Askew *et al.*,² three independent variables under the control of the surgeon determine cement intrusion characteristics: the magnitude of cement pressure, the duration of pressure application, and the cement viscosity.

Several investigators have shown that cement pressurization greatly improves cement intrusion characteristics.^{10,12,13} Krause *et al.*^{7,8} have demonstrated that low-viscosity cement has better intrusion characteristics.¹¹

Noble and Swarts have compared cement penetration depth in human cancellous bone plugs of known porosity for five commercially available cements. However, the specimens were tested at only one pressure level (5 PSI). This low pressure was well below the pressure levels achieved in clinical practice with either cement pressurization devices or even finger packing.¹² Furthermore, the influence of ambient temperature, monomer temperature, and cement centrifugation on cement intrusion depth into cancellous bone have not been documented.

In this study we compared cement intrusion in human and bovine cancellous bone plugs of various porosities using the same cement under the same conditions. We established a relationship between porosity and cement intrusion depth and related the bovine model to the corresponding human bone material. The bovine cancellous bone plug model offers many advantages. The bone is commercially available, is standardized, relatively inexpensive, and its mean porosity of 61% makes it a more stringent experimental model in terms of intrusion characteristics than human cancellous bone (porosity 81%–88% in our specimens).

The intrusion characteristics into bovine cancellous bone of three commercially available cements (LVC, Zimmer, Inc., Warsaw, IN; Simplex-P, Howmedica, Inc., Rutherford, NJ; Palacos, EM Labs, Inc., Elms Ford, NY) at three different insertion pressures (20, 40, and 60 PSI) reached in the operating room with commercial cement pressurization devices were investigated. The influence of monomer temperature, ambient temperature, and cement centrifugation on cement intrusion depth in a bovine cancellous bone model were also studied.

MATERIALS AND METHODS

Human cancellous bone plugs (19 mm length \times 12 mm diameter) were harvested from dried, defatted femoral head, proximal femur, distal femur, and proximal tibia specimens. The porosity of each specimen was determined by computer-assisted image analysis.⁶

Commercial bovine cancellous bone cylindrical plugs (19 mm length \times 12 mm diameter; Surgibone, Unilab Inc., Hillside, NJ) were selected by the same process in order to obtain standardized specimens with a porosity between 56% and 66% for actual testing. In order to see if there was a linear relationship between porosity and cement intrusion depth, bovine specimens outside this range were also tested. Each cylindrical plug was circumferentially wrapped with wax paper, leaving both ends open. For each test, three plugs of similar density were placed in series into a pressurization chamber where pressure was monitored by a pressure transducer (Fig. 1). Cement was delivered with a silicone coated Oh-Harris syringe mounted on a pneumatic piston. The syringe was secured to the pressurization chamber with clamps.

The predetermined pressure (20, 40, or 60 PSI) was attained almost instantaneously and applied for three seconds. Specimens were then retrieved and radiographed. Cement intrusion depth was measured in mm on the radiographs and corrected for magnification factor.

For LVC and Simplex-P, cement was prepared by adding the monomer to the powder in a stainless steel bowl and mixing at 2 Hz for 1 min as recommended by the manufacturer. For Palacos, manufacturer recommendations were also followed by adding the powder to the monomer. The liquid cement mixture was poured in the syringe and pressurized into the bone specimen 3 min after the beginning of mixing.

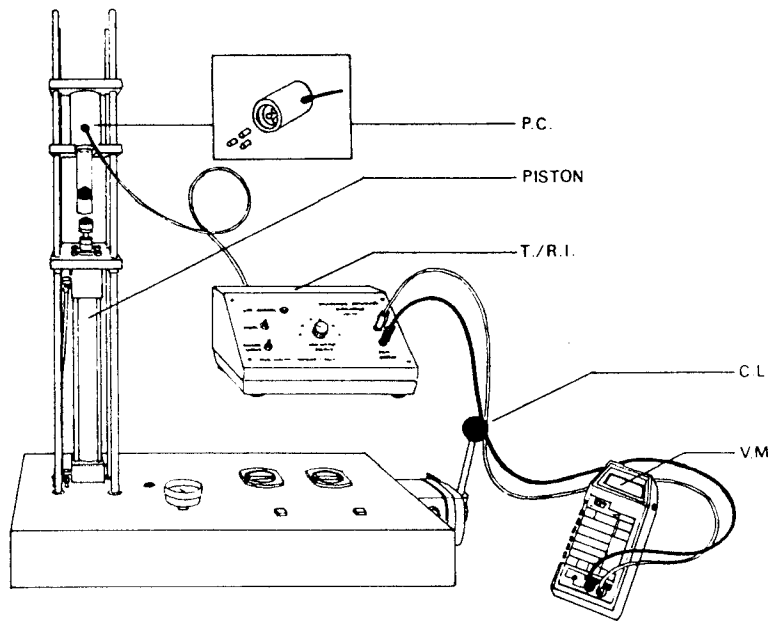


FIG. 1. Pressurization apparatus: P.C., Pressurization chamber with 3 bone specimens; T./R.I., Transducer/Recorder interface; C.L., Control Lever; V.M., Voltmeter.

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To compare human cancellous bone with bovine cancellous bone, Simplex-P cement was mixed at 22° ambient temperature and 65% relative humidity and intruded at 20 PSI pressure into 11 human bone plugs and 22 bovine bone plugs. All subsequent testing was done using bovine plugs.

LVC, Simplex-P, and Palacos were each tested at 20, 40, and 60 PSI pressure at 26° ambient temperature and 65% relative humidity. Simplex-P was also tested at 17° and 22° ambient temperature at the same three pressures and 65% relative humidity. Six specimens were tested for each set of experimental conditions.

The influence of chilling the monomer on cement intrusion was studied in the same fashion. Simplex-P and Palacos monomers were chilled to 0° by contact of the vials with ice for 2 hours. The monomer was mixed with powder at 22° ambient temperature and 65% relative humidity and tested at 20, 40, and 60 PSI intrusion pressure. Chilled LVC monomer was not tested because of the already low viscosity obtained at usual room temperatures with this cement.

The effect of centrifugation on cement intrusion was also studied in the same conditions (22° ambient temperature, 65% relative humidity) by mixing Simplex-P monomer (chilled to 0°) for 60 sec, centrifuging the mixture at 2000 RPM for 30 sec and then immediately injecting it. The centrifuged

cement was injected in six plugs each at each of three pressures (20, 40, and 60 PSI).

RESULTS

The 12 human cancellous bone plugs had a porosity ranging from 81.2% to 88.7%. In human bone, Simplex-P intrusion depth ranged from 10.8 mm to 17.4 mm when tested at 22° ambient temperature, 65% relative humidity and 20 PSI. Twenty-two bovine cancellous bone plugs with a porosity ranging from 57% to 81% were tested under identical conditions using the same cement. Cement intrusion depth was plotted against porosity (Fig. 2), demonstrating the relationship for cement intrusion into bovine and human bone.

From the studies in bovine cancellous bone, a direct relationship between cement intrusion depth and pressurization level was found for all three cements (Fig. 3). These differences were significant at $p < 0.005$ (Student's *t*-test) between pressures for the same cement and between various cements when tested at the same pressure. At each pressure, LVC intru-

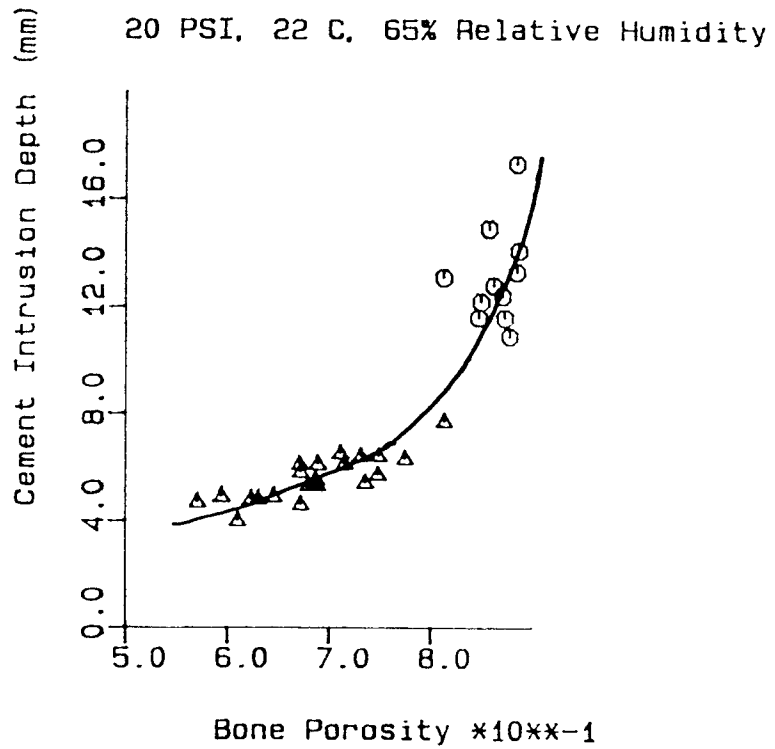


FIG. 2. Cement intrusion depth *versus* cancellous bone porosity plot using human specimens (○) and bovine specimens (△).

sion depth was greater than Simplex-P intrusion depth, which in turn was greater than Palacos intrusion depth. The standard deviations

were small; the maximum standard deviation was 12.0 ± 0.9 mm or 7.5% (Table 1).

Chilling the monomer increased cement

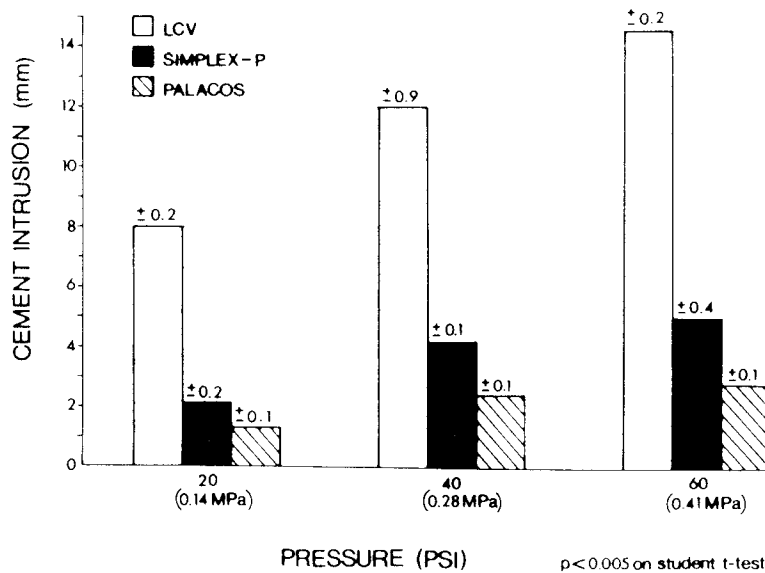


FIG. 3. Bar graph showing cement intrusion depth in bovine bone at different pressures for LVC, Simplex-P, and Palacos.

TABLE 1. Cement Intrusion Depth in Bovine Bone at Different Pressures for LVC, Simplex-P, and Palacos*

| Pressure | LVC | Simplex-P | Palacos |
|-------------------|---------------|--------------|--------------|
| 20 PSI (0.14 MPa) | 8.0 ± 0.2 mm | 2.2 ± 0.2 mm | 1.4 ± 0.1 mm |
| 40 PSI (0.28 MPa) | 12.0 ± 0.9 mm | 4.2 ± 0.1 mm | 2.4 ± 0.1 mm |
| 60 PSI (0.41 MPa) | 14.6 ± 0.2 mm | 5.0 ± 0.4 mm | 2.8 ± 0.1 mm |

* 26° ambient temperature, 65% relative humidity.
p < 0.005 on Student's *t*-test.

intrusion depth significantly for both Palacos (from 1.4, 2.4, and 2.8 mm to 4.2, 4.8, and 6.2 mm) and Simplex-P (from 2.2, 4.2, and 5.0 mm to 5.8, 8.2, and 12.7 mm) at all three pressures tested (Fig. 4). Cement centrifugation for 30 sec at 2000 RPM did not change the intrusion depth of Simplex-P cement in bovine bone at any of three pressures tested (Table 2).

Further significant increase in intrusion depth was obtained by lowering ambient temperature, and consequently the temperature of cement and the mixing equipment. Simplex-P intrusion depth was significantly increased by lowering the ambient temperature to 22° or 17° (65% relative humidity); from 2.2 mm at 26° to 5.1 and 6.3 mm at 22° and 17°, respectively, pressurizing at 20 PSI (Table

3). Those significant increases were also observed at 40 and 60 PSI (Fig. 5).

DISCUSSION

Extrapolations to the actual human situation must be prudently made because cancellous bone bed in the femoral canal *in vivo* is reduced by the reaming process. Our experimental model was more analogous to the acetabular cavity tibial plateau or femoral condyle in that regard. Fat and blood in the *in vivo* situation also produce some back pressure absent in our model and the bottom circular surface of our cylindrical specimen was open to the atmosphere. Trabecular orientation at the cancellous bone bed surface may also differ

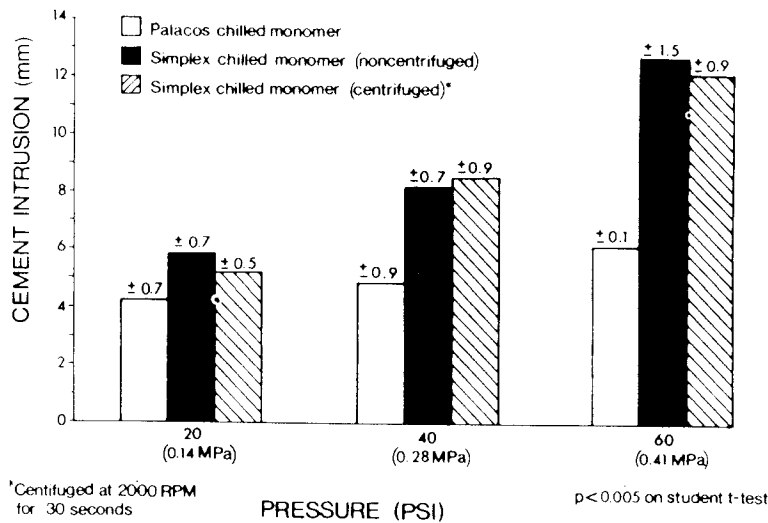


FIG. 4. Bar graph showing the effect of different pressures on cement intrusion in bovine bone using cement with monomer chilled to 0°.

TABLE 2. The Effect of Different Pressure on Cement Intrusion in Bovine Bone Using Cement with Monomer Chilled to 0°*

| <i>Pressure</i> | <i>Palacos Chilled Monomer</i> | <i>Simplex Chilled Monomer</i> | <i>Simplex Chilled Monomer**</i> |
|-------------------|--------------------------------|--------------------------------|----------------------------------|
| 20 PSI (0.14 MPa) | 4.2 ± 0.7 mm | 5.8 ± 0.7 mm | 5.2 ± 0.5 mm |
| 40 PSI (0.28 MPa) | 4.8 ± 0.9 mm | 8.2 ± 0.7 mm | 8.5 ± 0.9 mm |
| 60 PSI (0.41 MPa) | 6.2 ± 0.1 mm | 12.7 ± 1.5 mm | 12.1 ± 0.9 mm |

* 65% relative humidity.

** Centrifuged at 2000 RPM for 30 sec.

p < 0.005 on Student's *t*-test.

between the human and bovine specimens and planar porosity measurement does not take these differences into account. Nevertheless, for comparative purposes, the model appears valid because of the relationship between porosity and cement intrusion depth and its standardized porosity, which is further substantiated by the small standard deviations obtained in each set of experimental conditions. Moreover, it is important to realize that the bovine bone is substantially more dense than human trabecular bone.

This study demonstrates that in usual operating room conditions (22° and around 65% relative humidity) and using commercially available cement guns, a minimum cement intrusion depth of 5 mm in bovine cancellous bone can be obtained at 20 PSI with Simplex-P mixed for 60 seconds, poured into a cement syringe and injected.

Cement intrusion depth of 5 mm or more is greater than the usual bed of cancellous bone remaining in the femoral canal after prepa-

ration to receive a cemented femoral implant. Thus, increasing the intrusion depth by chilling the monomer or by using a cement of a lower viscosity in the clinical situation may not be necessary for femoral canal cementing. Cement centrifugation does not change cement intrusion characteristics, probably because it does not change cement viscosity in a noticeable way.

This study supports the view that a good cement intrusion depth is readily obtained by adequate pressurization, notwithstanding other factors such as ambient temperature, monomer chilling, or the type of cement use. It is clear, however, that factors other than cement intrusion may play a role in the decision to use cement made from monomer that has been chilled. One example is the prolonged working time at low viscosity. This can be a distinct advantage in complex situations such as the use of a long-stem prosthesis, which requires longer time to insert three or four packs of cement into the femur.

TABLE 3. Simplex-P Intrusion in Bovine Bone at Different Ambient Temperatures and Pressures*

| <i>Pressure</i> | <i>17° Ambient Temperature</i> | <i>22° Ambient Temperature</i> | <i>26° Ambient Temperature</i> |
|-------------------|--------------------------------|--------------------------------|--------------------------------|
| 20 PSI (0.14 MPa) | 6.3 ± 0.4 mm | 5.1 ± 0.3 mm | 2.2 ± 0.2 mm |
| 40 PSI (0.28 MPa) | 10.8 ± 0.3 mm | 6.3 ± 1.1 mm | 4.2 ± 0.1 mm |
| 60 PSI (0.41 MPa) | 16.4 ± 2.6 mm | 9.9 ± 1.0 mm | 5.0 ± 0.4 mm |

* 65% relative humidity.

p < 0.005 on Student's *t*-test.

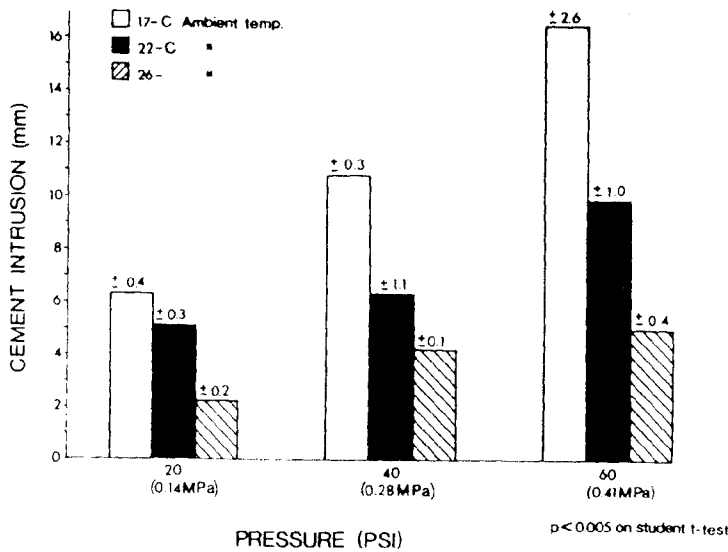


FIG. 5. Bar graph showing Simplex-P intrusion in bovine bone at different ambient temperatures and pressures.

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